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The Legal Authority of the United States Food and Drug Administration to Regulate Tobacco: Calling on Congress

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Smoking has plagued America for generations, but the issue has never received more scrutiny than in the past decade. The rise of teen smoking and the long-term deleterious effects of nicotine addiction prompted a national outcry for change. As a

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1 "Approximately 3 million American adolescents ... smoke ... [cigarettes, while] an additional 1 million adolescent males use smokeless tobacco [products]." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (1996) (footnote omitted) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897). "Eighty-two percent of adults who ... smoked ... their first cigarette [did so] before the age of 18, and more than half ... became regular smokers by that age." Id. (footnote omitted). Additionally, of those adolescent smokers between the ages of 12 and 17, "70 percent already regret their decision to smoke, and 66 percent say that they want to quit." Id. (footnote omitted).

2 For example, "[m]ore than 400,000 people die each year from tobacco related illnesses." Id. This means that "[t]obacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined." Id. (footnote omitted).

3 President Clinton announced an initiative to reduce youth smoking which contemplated the FDA's regulation of tobacco products under the Food Drug and Cosmetic Act. See Remarks Announcing the Final Rule to Protect Youth from
result, the United States Federal Food and Drug Administration (FDA) has asserted jurisdiction over the regulation of tobacco products.\(^4\)

The FDA, as one of the chief health regulatory agencies of the United States, is determined to take action to curb the nation's leading preventable killer.\(^5\) Due to the large number of adults addicted to cigarettes, however, an outright ban on tobacco would be both impractical and unrealistic.\(^6\) Therefore, acting on the findings of several major health organizations, the FDA determined the best way to curb the United States' addiction to nicotine was to stop it before it began.\(^7\) The resulting tobacco initiative included the regulation of the sale of tobacco products to minors, advertisement, and teen education cataloging the dangers of tobacco addiction.\(^8\)

The FDA's controversial regulatory scheme has prompted more public comment than any other agency-proposed regulation.\(^9\) Specific legislation granting the FDA authority to regulate tobacco products, however, has not occurred.\(^10\) Thus,


\(^5\) See id.; see also David A. Kessler et al., The Food and Drug Administration's Regulation of Tobacco Products, 335 NEW ENG. J. MED. 988, 991–93 (1996) (discussing the FDA's regulation restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents).

\(^6\) See Kessler, supra note 5, at 991. Health organizations estimate that "50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco [products]." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,398 (footnote omitted).

\(^7\) See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,398–99 (1996) [hereinafter Regulations Restricting the Sale of Tobacco]. The FDA posed an all out war on teenage smoking through regulations enacted to curb the sale of tobacco to minors. See id. at 44,399–400.

\(^8\) See Kessler, supra note 5, at 991–93; see infra text accompanying note 39.

\(^9\) See id. at 988. More than 700,000 comments were received regarding the proposed rules regulating tobacco products. See id.; Regulations Restricting the Sale of Tobacco, supra note 7, at 44,557. The initial comment period for the FDA's proposed regulation of tobacco products lasted 144 days. See id.

the final words regarding the regulation of tobacco will now emanate from Congress.\textsuperscript{11}

The FDA based its jurisdiction over tobacco products on the Federal Drug and Cosmetic Act's (FDCA) definitions of "drug"\textsuperscript{12} and "device."\textsuperscript{13} This article explores the ramifications of the FDA's assertion of jurisdiction. First, it reviews why the FDA has asserted jurisdiction over such products in the past and the judicial decisions reviewing its action. Second, it provides an in-depth analysis as to the Middle District of North Carolina's opinion in \textit{Coyne Beam, Inc. v. FDA},\textsuperscript{14} which allowed FDA jurisdiction, and the subsequent reversal by the Fourth Circuit in \textit{Brown \& Williamson Tobacco Corp. v. FDA}, which the United States Supreme Court has recently affirmed.\textsuperscript{15} It focuses on the different approaches taken by each court in interpreting whether tobacco products are a "drug" or "device" under the FDCA. This timely analysis is crucial as the case was recently decided by the United States Supreme Court.

\begin{footnotes}
\item[11] See \textit{FDA v. Brown \& Williamson Tobacco Corp.}, 120 S. Ct. at 1300, \textit{affg} 153 F.3d. at 176 (holding that the FDA does not have jurisdiction to regulate tobacco products).
\item[12] See 21 U.S.C. § 321(g)(1) (1994). The term "drug" in part means: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals." \textit{Id.} §§ 321(g)(1)(B), (C).
\item[13] See \textit{id.} § 321(h). The term "device" is defined in part as:
\begin{quote}
\begin{itemize}
\item an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
\end{itemize}
\end{quote}
\textit{Id.} §§ (h)(2), (3).
\end{footnotes}
I. BACKGROUND ON FDA TOBACCO REGULATION: THE WAFFLE EFFECT AND THE FOOD AND DRUG ADMINISTRATION'S CHANGE IN POLICY ASSERTING JURISDICTION

An indication that tobacco products posed a serious threat to human health surfaced in 1964, when the Surgeon General reported that smoking caused cancer in men and could also affect women in the same way. Congress acted swiftly in response to the report by passing the Federal Cigarette Labeling and Advertising Act in 1965, requiring warning labels on all cigarette packages. Soon thereafter, Congress banned cigarette advertising on television and radio.

The Surgeon General then began issuing new, more detailed warnings, which prompted the Federal Trade Commission to refine their labeling criteria to specifically reflect warnings about health consequences. The war on smoking evolved into a full-scale attack when several states enacted indoor clean air laws.

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17 See id. at 31.


20 Since 1964, the Surgeon General has issued 24 reports detailing the adverse effects of smoking. One such report outlined the adverse effects of smoking in young people. See U.S. DEP’T OF HEALTH AND HUMAN SERVICES, PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL 6–7 (1994).

21 See 15 U.S.C. § 1333(a)(1) (1988). Packages of cigarettes are required to bear one of the following labels:

- **SURGEON GENERAL'S WARNING**: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.
- **SURGEON GENERAL'S WARNING**: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
- **SURGEON GENERAL'S WARNING**: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.
- **SURGEON GENERAL'S WARNING**: Cigarette Smoke Contains Carbon Monoxide.

**Id.**

such as Pennsylvania’s Clean Indoor Air Act,\(^{23}\) to combat secondhand smoking’s adverse effects.

The findings concerning the dangers of smoking were so alarming that major health organizations declared war on cigarette smoking.\(^{24}\) The FDA entered the battle several times by asserting jurisdiction over tobacco products that promised increased health benefits associated with their use.\(^{25}\) For example, in *United States v. 354 Bulk Cartons*,\(^{26}\) the FDA asserted jurisdiction over cigarettes that promised appetite reduction and subsequent weight loss.\(^{27}\) The district court found that jurisdiction had been properly asserted where the manufacturer’s promises were based upon such weight reduction.\(^{28}\) The manufacturer intended the cigarettes to be used for therapeutic purposes. The court held that this satisfied the requisite intent of a drug under the FDCA as a product intended to affect the structure and function of the human body.\(^{29}\)

The FDA also asserted jurisdiction in *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*,\(^{30}\) when the manufacturer claimed through advertising leaflets that cigarettes were effective in preventing respiratory infections, circulatory disease, and other physical ailments.\(^{31}\) This advertisement was sufficient to bring the cigarettes under the second statutory meaning of a “drug,” which is a product intended to mitigate or prevent diseases.\(^{32}\)

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\(^{24}\) *See* Nicotine: Jurisdictional Determination, *supra* note 4, at 44,634 (discussing how all major public health organizations recognize the addiction caused by nicotine delivered through cigarettes and smokeless tobacco).

\(^{25}\) *See* e.g., Action on Smoking & Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980) (noting that “the FDA has asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers”).


\(^{27}\) *See id.* at 850 (promising that a user can “[s]afely lose up to twenty pounds or double your money back”) (citation omitted).

\(^{28}\) *See id.* at 851.

\(^{29}\) *See id.*; 21 U.S.C. § 321(g)(1)(C) (1994); *see also supra* note 12.


\(^{31}\) *See id.* at 337.

\(^{32}\) The advertisement implied that smokers would be less inclined to contract viral infections, like the common cold. *See id.* at 339 (determining that manufacturers could not “reap” the rewards of therapeutic claims without bearing responsibility for them); 21 U.S.C. § 321(g)(1)(B); *see also supra* note 12 (defining “drug”).
The fact that the FDA only asserted jurisdiction when cigarette manufacturers promised increased health benefits, prompted heated argument from a citizen's group called Action on Smoking and Health (ASH). This group filed suit pushing for the FDA's active assertion of jurisdiction over all tobacco products. The 1980 litigation resulted in the determination that the FDA lacked general jurisdiction over tobacco products. The court found no manifestation of the cigarette manufacturer's intent "to affect the structure or any function of the body of man." The FDA agreed that it lacked general jurisdiction over tobacco products because ASH had presented no evidence proving this requisite intent. The court interpreted the FDA's position against general regulation of tobacco, not as an indefinitely binding decision, but rather one reserved for a time when the proper showing of manufacturer intent could be established. Thus, this decision should be viewed as an indication of how times have changed, rather than as one that bars the FDA from asserting jurisdiction.

The FDA asserted general jurisdiction over tobacco products only after the majority of health organizations acted in concert to declare nicotine's harmful effects. In 1996, the FDA issued regulations to control teen smoking, including the prohibition of the sale of cigarettes to persons under age eighteen and the

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33 See Action on Smoking & Health v. Harris, 655 F.2d 236, 237 (D.C. Cir. 1980) (explaining that ASH, along with 13 other organizations and individuals, filed a citizen petition requesting that the agency assert jurisdiction over all cigarettes containing nicotine).

34 See id. at 243.

35 Id. at 239 (quoting 21 U.S.C. § 321(g)(1)(C)(1998)). The agency originally rejected ASH's request based on this lack of intent. See id. at 240. The district court agreed and denied the ASH petition. See id. at 243.

36 See id. at 239; see also id. at 240 (finding that ASH could not sustain the high burden of establishing the vendor's intent "to affect the structure or any function of the body of man" by consumer use). According to the court, ASH could meet this burden with "subjective vendor claims or objective evidence such as labeling, promotional material, and advertising," but not merely with consumer use. Id. at 239.

37 See id. at 239.

38 See Nicotine: Jurisdictional Determination, supra note 4, at 44,634. Several organizations recognized the addictive nature of nicotine in tobacco products. See id. The American Psychiatric Association began the movement in 1980. See id. Since 1981, the U.S. Surgeon General, the World Health Organization, and the American Medical Association, among others, submitted information to the FDA regarding the addictive properties of nicotine. See id.
regulation of advertisement geared toward minors. As the FDA has based its jurisdiction on the FDCA’s definitions of “drug” and “device,” a clear understanding of the problem requires a close examination of these definitions.

The FDA has met with litigation over the validity of its assertion of jurisdiction over nicotine products. In Coyne Beahm, Inc. v. Food & Drug Administration, the district court determined, based on judicial history, legislative intent, and product use, that the FDA properly asserted jurisdiction over tobacco products. The Coyne court discussed the meaning of “drug” and “device” under the FDCA and applied evidence of foreseeable use, actual use, and manufacturer representations to determine that tobacco products are intended to affect the structure or function of the body. The court also found that congressional intent reinforced their findings, based on Congress’ acquiescence to agency interpretation. Manufacturers appealed this ruling, maintaining that nicotine-containing products do not fall under the definition of “drug” or “device” and thus, should escape regulation by the FDA.

Agreeing with the Fourth Circuit in Brown & Williamson Tobacco Corp. v. Food & Drug Administration, the United States Supreme Court held that the FDA lacked jurisdiction over tobacco products, because the measure lacked the requisite congressional intent required to execute the regulatory

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40 See supra notes 29, 35–37 and accompanying text (discussing the manufacturer’s requisite intent to affect the structure or function of the body, which is found in the FDCA’s definition of device).
43 See id. at 1379–88.
44 See id. at 1388–91, see also supra notes 29, 35–37 and accompanying text.
45 See Coyne Beahm, Inc., 966 F. Supp. at 1391 (finding that “[t]he plain language and the legislative history of the drug and device definitions do not reveal that Congress clearly intended for FDA to rely only upon evidence of manufacturer representations to establish intended use”).
46 See Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155 (4th Cir. 1998), aff’d 120 S. Ct. 1291 (2000).
47 Id.
Both the United States Supreme Court and the Fourth Circuit denied the FDA jurisdiction over tobacco products due to "fundamental conflicts" and several "internal inconsistencies" in the FDA's regulatory scheme. Thus, the judiciary has determined that the FDA lacks jurisdiction over tobacco products, despite its strong showing of compatible, existing regulatory provisions and convincing evidence of the danger of nicotine addiction.

Examination of the FDA's asserted jurisdiction of tobacco regulation requires an analysis similar to that in Coyne. This analysis considers tobacco's foreseeable use, actual consumer use of the product, and the content of internal manufacturer memoranda. The serious health risks associated with tobacco products and the unique hold tobacco has on Americans, warrant a detailed examination of multiple factors, not simply congressional intent. The district court properly considered many factors in its determination, including the plain language of the statute, the effect of tobacco on users, as well as, congressional intent.

The regulation of tobacco products poses a problem because tobacco is a profitable business for the economy. The tobacco industry generates fifty-four billion dollars in annual revenue. This wealth allows the industry to create tremendous political

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49 Id. at 1302 (noting that because the FDA also claimed tobacco was unsafe, it was impossible for it to implement regulations that would provide "reasonable assurance[s] of safety"), aff'd 153 F.3d 155, 164 (4th Cir. 1998).
50 Id. at 1299 (discussing the FDA's vacillation in classifying tobacco both as a "drug" or "device" depending on which classification suited their purposes at the time), aff'd Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 164-67 (4th Cir. 1998).
51 See id. at 1299, aff'd Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 167 (4th Cir. 1998).
53 See id. at 1391 (declaring that "foreseeability, actual consumer use, and internal manufacturer memoranda" must be examined in addition to legislative history and judicial construction).
54 See Peter S. Arno et. al., Tobacco Industry Strategies to Oppose Federal Regulation, 275 JAMA 1258, 1260 (1996). This income, in turn, pays $12 billion in taxes. See id.
pressure, \(^5^5\) in the form of lobbying, delays, and filibusters, thereby forcing the failure of much tobacco legislation. \(^5^6\)

It still appears that the FDA is the obvious choice to regulate the tobacco industry, as the FDCA's broad regulatory authority already grants the FDA the power to assert jurisdiction over "drugs" and "devices." \(^5^7\) In fact, the FDA already regulates almost every object placed into or around the human body. \(^5^8\) The FDA maintains that cigarettes fall within the "drug" and "device" classifications of the FDCA because nicotine is intended to affect the structure or function of the body. \(^5^9\)

Tobacco manufacturers objected to this assertion of authority and claimed tobacco products simply did not fit under the statutory definitions. \(^6^0\) Despite previous court rulings, including the recent landmark United States Supreme Court decision,

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\(^5^5\) The tobacco industry also maintains a powerful agricultural impact and plays a dominant role as large subsidiaries of other manufacturing companies. See id. It also finances campaigns to influence the political process. See id. at 1261.

\(^5^6\) On May 18, 1998, Congress introduced the National Tobacco Policy and Youth Smoking Reduction Act. See 144 CONG. REC. S5001 (daily ed. May 18, 1998). This act was meant to "reform" and "restructure" tobacco production and marketing processes in an effort to prevent the underuse of tobacco products. See id. The bill subsequently failed on June 17, 1998, as a result of 40 million dollars spent by the tobacco industry in lobbying to "hijack the process." 144 CONG. REC. S6485 (daily ed. June 17, 1998) (statement of Sen. Murray).


\(^5^8\) The FDA regulates products that are "ingested, inhaled, implanted, or otherwise used in close contact with the human body." Nicotine: Jurisdictional Determination, supra note 4, at 44,628. This includes products such as "foods, drugs, medical devices, and cosmetics." See id.; see also 21 U.S.C. §§ 321(f), (g)(1), (h) and (i) (1994) (defining "food," "drug," "device," and "cosmetic" within the Federal Food, Drug, and Cosmetic Act respectively). The U.S. Department of Agriculture also retains regulatory authority over some specific foods such as meat and dairy products. See 7 U.S.C. §§ 1-5106 (1994).

\(^5^9\) See Nicotine: Jurisdictional Determination, supra note 4, at 44,629.

\(^6^0\) See George Johnson, With Tobacco, It's Time to Trust Congress to Do the Right Thing, ST. LOUIS POST-DISPATCH, June 6, 1996, at B3 (noting that "[t]he tobacco industry argues ... that the FDA does not have the legal authority to regulate cigarettes, as Congress has not specifically given the FDA the authority to regulate nicotine as a drug"), available in 1999 WL 3027246; Robert S. Greenberger & Suein L. Hwang, Court to Rule on FDA Role Over Tobacco, WALL ST. J., Apr. 27, 1999, at A3 (providing the legislative intent argument of tobacco manufacturers). Although the district court in Coyne rejected this argument, the court of appeals agreed with tobacco companies and concluded that the "FDA [was] attempting to stretch the Act beyond the scope intended by Congress." Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 167 (4th Cir. 1998), aff'd FDA v. Brown & Williamson Tobacco Corp., 120 S. Ct. 1291 (2000).
which held that the FDA did not have jurisdiction to regulate tobacco, new evidence of manufacturer representations and the addictive qualities of cigarettes could now provide a basis for Congress to accept the FDA's contention. The agency's new findings and liberal interpretation of the FDCA make the FDA's classification of tobacco as a "drug" or "device" proper and timely. Further, the overall intent of the FDCA is premised on public protection. As the United States Supreme Court in *Kordel v. United States* enunciated, "[t]he high purpose of the Act [is] to protect consumers who under present conditions are largely unable to protect themselves." Nevertheless, the complexity of the FDA assertion of jurisdiction over tobacco continues to spur argument and controversy.

The FDA determined that it had jurisdiction over tobacco as a combination drug and device, as it considered nicotine a drug, and cigarettes and smokeless tobacco products as drug delivery devices. The analysis of whether the FDA can validly assert jurisdiction over tobacco products must be examined on two levels. Despite the United States Supreme Court's ruling, the

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61 See e.g., *Action on Smoking & Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

62 See Jan Crawford Greenburg & Peter Gorner, *Tackling Tobacco: The Supreme Court Agrees to Decide One of the Most Contentious Health Issues in America—Whether the Government Has the Authority to Regulate Tobacco*, CHICAGO TRIB., Apr. 27, 1999, at 1 (discussing the Supreme Court decision to grant certiorari amid the recent scientific findings), available in 1999 WL 2867370; see also Laurie Asseo, *Court to Rule on Smoking Dispute: Government, Cigarette Industry to Spar Over Whether FDA Can Regulate Tobacco*, FORT WORTH STAR-TELEGRAM, April 27, 1999, at 3 (noting that "[t]he government says . . . [there is] new evidence that the tobacco industry intends its products to feed consumers' nicotine habits"), available in 1999 WL 6231880.

63 *335 U.S. 345 (1948).*

64 Id. at 349 (citation omitted). Other United States Supreme Court decisions have recognized the importance of consumer protection. For example, in *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969), the Supreme Court stated: "We are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.

Similarly, in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 158 (1958), the Court declared: "We granted certiorari to determine . . . construction of this important statute designed for the protection of the public health." The circuit courts have also recognized the importance of protection. In *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988), *cert. den.* 488 U.S. 924 (1988), the Eleventh Circuit concluded that "[t]he general scheme of the Act and its legislative history indicate that the overriding congressional purpose was consumer protection."

65 *See Nicotine: Jurisdictional Determination, supra* note 4, at 44,629.
initial inquiry still concerns whether the FDA should even have jurisdiction to regulate tobacco products. A starting point for this issue is to examine the statutory definitions of "drug" or "device," and determine whether nicotine-containing products meet these criteria. Congress's impact on administrative regulatory schemes also plays a vital role in determining whether the FDA possesses the power to regulate tobacco.

The focal point of FDA regulation centers on nicotine, the addictive ingredient in cigarettes and smokeless tobacco. The FDA maintains that tobacco products meet the "drug" or "device" criteria because they are intended to affect the structure or function of the body. The FDA issued these findings based on information discovered from industry records and a consensus of health organizations that have joined forces in asserting the addictive properties of nicotine. The FDA further argued that tobacco products meet the "drug" and "device" criteria due to the manufacturer's intent for consumers to use their products as a combination device. Although the Coyne court agreed with the FDA's assessment in determining that tobacco products fall under the FDA's jurisdiction, the Fourth Circuit and the United States Supreme Court rejected this argument. The Supreme Court and the court of appeals used very different approaches in analyzing the problem of the FDA's assertion of jurisdiction over tobacco than

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6 See id. at 44,629.
67 See id. The American Medical Association (AMA) urged the FDA to regulate tobacco products and help reduce nicotine's addictive potential. See Jim Ritter, AMA Wants Nicotine Curb, Goal: Less-Addictive Cigarettes, CHI. SUN TIMES, June 19, 1998, at 18, available in 1998 WL 5585925. The AMA noted that 70% to 80% of smokers want to quit, but cannot because they are "hooked" on nicotine. See id.
68 See supra note 38 and accompanying text; see also Nicotine: Jurisdictional Determination, supra note 4, at 44,629 (finding that there has been an "emergence of a scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine").
69 See Nicotine: Jurisdictional Determination, supra section III (discussing consumer use as a factor in assessing FDA jurisdiction over tobacco products).
71 See FDA v. Brown & Williamson Tobacco Corp., 120 S. Ct. at 1299, 1301, aff'g 153 F.3d 155, 175–76 (4th Cir. 1998). The court of appeals did not discuss the manufacturer's intent. See id. at 163 (noting only that the FDA did not assert that the manufacturers intended their products to affect the structure and function of the body).
did the district court. Both courts determined that statutory interpretation was the threshold of the analysis, and if the legislative history did not encourage regulation, the product should not be regulated.\textsuperscript{72} The district court found that the FDA's theories of regulation comported with elements such as foreseeable use and actual consumer use, which could not be ignored.\textsuperscript{73} The Coyne court accepted the FDA's position that relied on foreseeable use, actual consumer use, and manufacturer representations to establish intended use.\textsuperscript{74} Furthermore, agency interpretation and judicial decisions do not prohibit the FDA from considering other evidence to prove intended use.\textsuperscript{75} According to the district court, the legislative history and the definitions of "drug" and "device" do not indicate that Congress meant for the FDA to rely solely on evidence of manufacturer representations to establish intended use.\textsuperscript{76} The Supreme Court and the Fourth Circuit, however, rejected this analysis and narrowed the scope of inquiry to the historical role and actions of the FDA in relation to tobacco regulation and prior congressional actions.\textsuperscript{77} The courts ultimately decided that the FDA lacked jurisdiction over tobacco based on legislative intent,\textsuperscript{78} choosing to ignore the vital factors of consumer use, foreseeable use and manufacturer memoranda, and information from newly emergent scientific findings concerning tobacco and its effect on the American public.

\textsuperscript{72} See \textit{id.} at 1299-1300, aff\textsuperscript{g} Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 163 (4th Cir. 1998).

\textsuperscript{73} See \textit{Coyne Beahm, Inc.}, 966 F. Supp. at 1391-92.

\textsuperscript{74} See \textit{id.} at 1391.

\textsuperscript{75} See \textit{id.} at 1391-92.

\textsuperscript{76} See \textit{id.}; see also \textit{Chevron USA, Inc. v. Natural Resources Defense Council, Inc.}, 467 U.S. 837, 845 (1984) (noting that "[o]nce [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], . . . the question before it [is] . . . whether the [agency's] view . . . is a reasonable one").

\textsuperscript{77} See \textit{FDA v. Brown & Williamson Tobacco Corp.}, 120 S. Ct. at 1294-95, aff\textsuperscript{g} 153 F.3d 155, 160-70 (4th Cir. 1998). Since 1914, the FDA had continually asserted that tobacco products were outside the scope of its jurisdiction unless marketed with health claims. \textit{See e.g.}, \textit{Action on Smoking & Health v. Harris}, 655 F.2d 236, 239 (D.C. Cir. 1980); \textit{Federal Trade Comm'n v. Liggett & Myers Tobacco Corp.}, 108 F. Supp. 573, 575 (S.D.N.Y. 1952), aff\textsuperscript{d}, 203 F.2d 955 (2d Cir. 1953).

\textsuperscript{78} See \textit{FDA v. Brown & Williamson Tobacco Corp.}, 120 S. Ct. at 1297, aff\textsuperscript{g} 153 F.3d 155, 175-76 (4th Cir. 1998).
II. THE ROLE OF CONGRESSIONAL INTENT OR CONGRESSIONAL INACTION IN AFFORDING EXPLICIT AUTHORITY TO REGULATE BY THE FOOD AND DRUG ADMINISTRATION

Brown & Williamson rejected the lower court's analysis in Coyne, as well as the FDA's contention that Congress' lack of explicit delegation of authority to regulate tobacco did not negate its jurisdictional authority.79 The Fourth Circuit stated that both the FDA and the district court used only a "mechanical reading" approach to interpret the definition of "drug" and "device" under the FDCA.80 The United States Supreme Court and the court of appeals recognized that the FDA was charged with protecting the public health from harmful drugs and devices, but ultimately rejected the FDA's chosen method of regulation.81 The court determined that the FDA should weigh the risks and benefits of the use of a particular product and not balance the effects of removing that product from the market.82 The Supreme Court and the Fourth Circuit disagreed with the FDA's interpretation of why tobacco falls within its regulatory authority, and also determined that the FDA lacked the power to make this "major policy decision."83 Both courts concluded that the FDA went beyond the authority granted to it by Congress.84

The determination of the FDA's jurisdiction over tobacco products focuses on an analysis of congressional intent. Despite these judicial determinations, it seems that the nature of the FDA's timely control, coupled with the broad powers of the FDCA, indicate that the FDA's assertion of jurisdiction still coincides with legislative intent.85 The Supreme Court in

79 See id. at 1298-99, affg 153 F.3d 155, 175-76 (4th Cir. 1998).
80 See Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 163 (4th Cir. 1998).
82 See Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d at 164 (4th Cir. 1998) (noting that "by statute, the FDA's authority is limited to the balancing of health benefits and risks"); see also 21 U.S.C. § 360c(a)(2)(C) (1994) (expressing that the "weighing [of] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use" determines the suitability of devices on the market).
83 Brown & Williamson Tobacco Corp., 153 F.3d at 176.

The two-prong test established by *Chevron* for analyzing congressional intent begins with a determination as to whether Congress has spoken clearly on the issue at hand. If so, "that is the end of the matter." If, however, Congress left a gap in the statutory interpretation, or if the intent of Congress is ambiguous, then the agency responsible for issuing regulations may fill this void. Defeference to the agency's regulations is permissible unless the construction is "arbitrary, capricious, or manifestly contrary to the statute." Thus, a court may not substitute its own statutory interpretation for that of the agency if the agency's construction is reasonable.

Applying the *Chevron* analysis to tobacco regulation begins with a determination as to whether Congress has clearly spoken regarding the FDA's jurisdiction over tobacco products. The United States Supreme Court agreed with the tobacco manufacturers' contention that Congress never authorized nor intended for the FDA to assert jurisdiction over tobacco products. The Court further agreed with the contention by tobacco manufacturers that if Congress intended the FDA to regulate tobacco, then acquiescence to the FDA's jurisdiction over tobacco would have been included in either the Cigarette Labeling and Advertising Act, the Comprehensive Smokeless

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87 See id. at 842–44. Chevron challenged the Environmental Protection Agency's Clean Air Act and the stringent conditions on air quality as well as the use of equipment to nullify pollution emitting devices. See id. at 840.
88 See id. at 842.
89 Id.
90 See id. at 843–44.
91 Id. at 844.
92 See id.
94 See FDA v. Brown & Williamson Tobacco Corp., 120 S. Ct. at 1298-99; 15
Tobacco Health Education Act,95 or the Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992 (the "Acts").96 The Coyne court found that the FDA's tobacco regulations did not conflict with the text of the Acts.97 Additionally, the Acts did not evidence congressional intent to withhold jurisdiction from the FDA to regulate tobacco products.98

Second, the tobacco companies argued that because the legislation failed to grant jurisdictional authority to the FDA, Congress explicitly did not intend the FDA to have jurisdiction over tobacco products.99 Despite evidence that Congress has repeatedly failed to pass legislation granting such jurisdiction to the FDA, the Coyne court rejected this argument,100 explaining that unenacted legislation did not indicate congressional intent.101 The United States Supreme Court and the Fourth Circuit both disagreed with the Coyne court.

The lack of clear congressional intent forced the district court in Coyne to move to the second prong of the Chevron test.102 The Coyne court examined the FDA's reasoning behind its assertion of jurisdiction over tobacco as a "drug" and "device."103 Unlike the United States Supreme Court and the Fourth Circuit, the Coyne court accepted the FDA's argument that evidence of actual use and foreseeable use constituted an independent basis for "intended use" under the FDCA.104 The district court also found that though the FDA had changed its position regarding its authority to regulate tobacco products since the 1980 ASH

98 See id. at 1388; see also supra note 76.
99 See supra notes 46–51 and accompanying text. The power of the tobacco industry can be seen in Congress' inaction. This inaction, however, does not mean that Congress does not believe the FDA has the power to regulate tobacco. See generally Brecht v. Abrahamson, 507 U.S. 619, 632 (1993) (warning against drawing inferences from congressional inaction).
100 See Coyne Beahm, Inc., 966 F. Supp. at 1382.
102 See id. at 1388 (engaging in statutory interpretation in the face of a lack of clear congressional intent).
103 See id. at 1392.
104 See id. at 1384.
decision,\textsuperscript{105} this change was not arbitrary or capricious\textsuperscript{106}—the Supreme Court determined otherwise.

The district court in \textit{Coyne} relied on \textit{Chevron}'s reasoning in noting that “[a]n initial agency interpretation is not instantly carved in stone.”\textsuperscript{107} Rather, “[an] agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis.”\textsuperscript{108} The FDA waited to assert general jurisdiction until new findings of nicotine addiction indicated scant scientific doubt regarding the adverse effects of nicotine in tobacco products on the structure or function of the body.\textsuperscript{109}

It appears that the \textit{Coyne} district court's decision, unlike the United States Supreme Court and the court of appeals in \textit{Brown \& Williamson}, is consistent with previous rulings regarding the jurisdictional determination of tobacco regulation,\textsuperscript{110} which have looked at jurisdictional determination within the context of congressional intent.\textsuperscript{111} As previously mentioned, “[a]n

\textsuperscript{105} See \textit{Action on Smoking \& Health v. Harris}, 655 F.2d 236, 237 (D.C. Cir. 1980) (discussing the FDA's refusal to assert jurisdiction over nicotine under section 201(g)(1)(C) of the FDCA).

\textsuperscript{106} \textit{Coyne Beahm, Inc.}, 966 F. Supp. at 1384 (describing the change in position as “reasonable”); \textit{Nicotine: Jurisdictional Determination: supra} note 4 at 44,619, 45,219 (including new medical findings of nicotine's addictive properties which helped to develop a new attitude toward the regulation of tobacco products by the FDA). The Supreme Court in \textit{Chevron} also articulated that an agency is entitled to change its policies. See \textit{Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.}, 467 U.S. 837, 863–64 (1984).

\textsuperscript{107} \textit{Coyne Beahm, Inc.}, 966 F. Supp. at 1384 (quoting \textit{Chevron}, 467 U.S. at 863–64).

\textsuperscript{108} \textit{Id.}

\textsuperscript{109} See \textit{Nicotine: Jurisdictional Determination, supra} note 4, at 45,219–22.

\textsuperscript{110} See \textit{Coyne Beahm, Inc.}, 966 F. Supp. at 1384; \textit{Action on Smoking \& Health}, 655 F.2d at 242 (recognizing the appropriateness of judicial deference to the FDA's changing opinion). Further, \textit{Brown \& Williamson} gave little deference to \textit{Chevron}, and gave greater weight to the FDA's original refusal to assert jurisdiction. See \textit{Brown \& Williamson Tobacco Corp. v. FDA}, 153 F.3d 155, 169–70 (4th Cir. 1998), \textit{aff'd} No. 99-1152, 2000 WL 289576 (U.S.N.C. Mar. 21, 2000).

\textsuperscript{111} See \textit{Coyne Beahm, Inc.}, 966 F. Supp. at 1384. The court discussed several decisions, which examined drug and device regulation. \textit{See id.} at 1388–92. One such case was \textit{National Nutritional Foods Ass'n v. Mathews}, 557 F.2d 325, 330 (2d Cir. 1977), which examined vitamins to determine whether they should be regulated under the FDCA's definition of a drug. The \textit{Mathews} court found that in determining whether a drug is intended for use as a drug, the FDA is not bound by manufacturer's subjective claims but may also rely on objective evidence. \textit{See id.} at 334. The use of a drug for exclusively therapeutic purposes is sufficient to show intent for use in the treatment of disease. \textit{See id.} at 1335. Ultimately, the appellate court found that the FDA could assert jurisdiction over high dosage vitamins. \textit{See id.}
administrative agency is clearly free to revise its interpretations." The ASH court noted, "[n]othing in this opinion should suggest that [the FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch." Although the FDA declined jurisdiction over nicotine containing products in 1980, it had the ability to alter its position if and when evidence appeared that made the FDA's assertion of jurisdiction timely and proper.

The Coyne court buttressed the FDA's statutory interpretation by clarifying that the FDCA was intended to broaden former food and drug laws. The intent of Congress to broaden the statutory definition of a drug is illustrated in United States v. Bacto-Unidisk. The Supreme Court noted, after examining the product at hand and medical definitions of "drug," that "Congress intended to define 'drug' far more broadly than does the medical profession." Bacto-Unidisk laid the foundation for Coyne's reasoning that if Congress intended a strictly medical usage for the term "drug," it would have explicitly stated so in the FDCA.


Action on Smoking & Health, 655 F.2d at 242 n.10.


394 U.S. 784 (1969). The Supreme Court examined whether or not antibiotic sensitivity disks, used to determine the proper antibiotic to administer to patients would be considered a "drug" under the FDCA. See id. at 787-88. The product never touched the body, but was used in connection with the patient's specimen. See id. at 787.

Id. at 793. The Supreme Court went on to add that the addition of a "device" definition that almost paralleled the "drug" definition helped the Court reach this conclusion. See id.

See id. at 793-94.
The *Coyne* court noted that another purpose of the FDCA was to protect the public from problematic devices.\(^{119}\) Clearly, the FDCA is an act aimed at public protection.\(^{120}\) The appearance of internal manufacturer memoranda listing the dangers of cigarettes and smokeless tobacco\(^{121}\) bolsters the public protection basis of the FDCA, thus qualifying nicotine as a regulated product. The district court in *Coyne* correctly found the FDA's statutory interpretation acceptable.\(^{122}\)

Finding that the FDA had proper jurisdiction is consistent with the legislative history. The hurdle of regulation still lingers, leaving both proponents and adversaries of the FDA's tobacco regulation wondering what comes next.

### III. Consumer Use as a Factor in the Determination of Whether the Food and Drug Administration Has the Legal Authority to Regulate Tobacco

Tobacco companies assert that the FDA cannot consider consumer use in determining whether tobacco products meet the "drug" or "device" criteria.\(^{123}\) The district court in *Coyne* disagreed, finding that actual consumer use was a vital factor in analyzing whether the FDA has jurisdiction over tobacco products.\(^{124}\) The *Brown & Williamson* courts agreed with the manufacturers and did not analyze the role of actual consumer use in determining the FDA's jurisdiction over tobacco products.\(^{125}\) The discrepancy between the appellate and district courts on the issue of actual consumer use plays a major role in the determination of which court has the most persuasive, and

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\(^{119}\) See *Coyne Beahm, Inc.*, 966 F. Supp. at 1392–93.

\(^{120}\) See *supra* note 58 and accompanying text.

\(^{121}\) See *Nicotine: Jurisdictional Determination*, *supra* note 4, at 44,847–915 (discussing statements and research of each of the major cigarette companies and the Council for Tobacco Research, which shows that cigarette manufacturers know of the dangers of tobacco use, and that they intend their products to have pharmacological effects on the bodies of the consumers); see also *id.* at 45,098–150 (discussing evidence from smokeless tobacco producers on intentional "graduation" of nicotine levels to promote tolerance and addiction).

\(^{122}\) See *Coyne Beahm, Inc.*, 966 F. Supp. at 1393.

\(^{123}\) See *id.* at 1391; see also *Nicotine: Jurisdictional Determination*, *supra* note 4, at 45,160–61.

\(^{124}\) See *Coyne Beahm, Inc.*, 966 F. Supp. at 1391–92 (stating that the cases relied upon by the tobacco companies are not on point).

perhaps, most politically correct analysis. The determination of the proper analysis of the FDA’s jurisdiction over tobacco products now lies with Congress.

Previous courts have found that actual consumer use plays an important role in determining FDA jurisdiction. For example, the court in United States v. 22 Devices “The Ster-O-Lizer MD-200” addressed whether a product used to sterilize surgical equipment could be regulated by the FDA as a device. The district court noted, “[t]he objective intent referred to in the regulation may be shown not only by a product’s labeling claims, advertising or written statements relating to the circumstances of a product’s distribution, but also by a product’s actual use.” The Ster-O-Lizer case illustrated that objective intent looks further than a product’s label, into the heart of its purpose.

The ASH court noted that statutory intent could be inferred when consumers use a product exclusively and with a specific purpose. A finding that consumers use cigarettes as a drug corroborates the FDA’s claims of actual use. The FDA found that 77% to 92% of smokers and 75% of smokeless tobacco users are addicted to nicotine. According to the FDA, one third to one half of young smokers use smoking for weight control, and 50% of

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125 See, e.g., United States v. 22 Rectangular or Cylindrical Finished Devices, More or Less, “The Ster-O-Lizer MD-200,” Halogenic Products Co., 714 F. Supp. 1159, 1165 (D. Utah 1989) [hereinafter Ster-O-Lizer] (holding that the test to see if a product is a device, and, thus, subject to FDA jurisdiction, is based “solely on the product’s intended use”); see also National Nutritional Foods Ass’n v. Weinberger, 512 F.2d 688, 703–04 (2d Cir. 1975) (holding that near exclusive consumer use is evidence of intended use).


127 See id. at 1161.

128 See 21 C.F.R. § 801.4 (1998) (stating that the objective intent of the manufacturer can be determined by examining the manufacturer’s expressions, the way in which they distribute the product, and the purpose behind their actions).

129 Ster-O-Lizer, 714 F. Supp. at 1165. The court examined, in conjunction with device definitions, those provisions of the Code of Federal Regulations that discuss the meaning of “intended use,” including volume 21, sections 801.4, 801.5, 801.119, 801.122. See id. The sections refer to intended use as “the objective intent of the persons legally responsible for the labeling of devices” and how this objective intent can be derived. Id. (quoting 21 C.F.R. § 801.4 (1998)) (emphasis added).

130 See id.

131 See Action on Smoking & Health v. Harris, 655 F.2d 236, 240 (D.C. Cir. 1980).

132 See Nicotine: Jurisdictional Determination, supra note 4, at 44,635–36.
young people utilize smokeless tobacco for relaxation. FDA findings also indicate that of those smokers aged ten to twenty-two, 70% use cigarettes for relaxation. Thus, actual consumer use substantiates use that affects the structure or function of the body. Agnew v. United States confirmed that "intended for use" could be inferred from one's actions by concluding that "[t]he law presumes that every man intends the legitimate consequence of his own acts." The proposition that one's actions foretell intention has long been a part of this legal theory and should similarly apply to tobacco product regulation.

IV. FORESEEABILITY AS A FACTOR IN GRANTING THE FDA THE AUTHORITY TO REGULATE

Another factor in the FDA's assertion of jurisdiction to regulate tobacco products is based on the foreseeable effects of tobacco products, which can be used to prove a manufacturer's intent. FDA evidence has indicated that manufacturers' design of cigarettes and smokeless tobacco, combined with a potent dosage of nicotine, show that they foresaw consumer addiction. The district court in Coyne made clear that, although Congress did not specifically state that foreseeable use could be considered for determining intended use, nothing prohibits it. The court of appeals and the United States Supreme Court did not address foreseeable use in their tightly woven opinions.

The lack of discussion of foreseeable use has left the FDA and proponents of the FDA's jurisdiction over tobacco without

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134 See id. at 44,635–36.
135 See id. at 44,636.
136 165 U.S. 36 (1897).
137 See id. at 53.
138 Id.
139 See Nicotine: Jurisdictional Determination, supra note 4, at 44,633–34 (discussing the pharmacological effects of tobacco on the human body, such as the addictive nature of nicotine, and that the tobacco industry's denial of such effects can not be believed in light of the overwhelming scientific evidence).
140 See id. at 44,636–42.
one of their most powerful and convincing arguments for the assertion of jurisdiction to regulate tobacco. The Supreme Court and the Court of Appeals in Brown & Williamson appellate courts based their decisions on the fact that Congress has had many instances to act on tobacco regulation, and its inaction, as applied to the FDA, indicated specific intent to deny the agency regulatory authority.143

The foreseeability test that the FDA relied on stems from evidence that nicotine is addictive and causes "significant pharmacological effects."144 The FDA also noted that nicotine could have mood altering effects and other qualities that parallel those of opiates.145 Today, findings of the powerful, addictive nature of nicotine emanate from health agencies.146 Nicotine is identified by all the pertinent expert organizations as one of the few truly dependence-producing drugs, occupying the list with cocaine, heroin, and alcohol.147 Thus, the "scientific consensus" and consumer use patterns indicate that manufacturers do foresee that their products have addictive qualities and that consumers use tobacco products for their pharmacological properties.

V. INTERNAL MANUFACTURERS' MEMORANDA AS A FACTOR IN FDA REGULATION

Perhaps the most compelling evidence of manufacturers' intent is their memoranda. Nevertheless, the Fourth Circuit and the United States Supreme Court did not squarely address this issue. The Fourth Circuit simply concluded that manufacturers do not intend for their products to be used as a "drug" or "device."148 The FDA relied on research and memoranda from

143 See id. at 1306-14, affg 153 F.3d 155, 160 (4th Cir. 1998); see also supra note 49 and accompanying text.
144 Nicotine: Jurisdictional Determination, supra note 4, at 44,634.
145 See id. at 44,635.
146 See id. at 44,634 (noting that, "[s]ince 1980, nicotine in tobacco products has also been recognized as addictive by the U.S. Surgeon General (1986 and 1988), the American Psychological Association (1988), the Royal Society of Canada (1989), the World Health Organization (1992), the American Medical Association (1993), and the Medical Research Council in the United Kingdom (1994)").
147 See id. at 44,701-12 (discussing the criteria and classification of many addictive substances, including nicotine).
148 See Brown & Williamson Tobacco Corp., 153 F.3d at 160-161 (4th Cir. 1998) (reasoning that Congress has spoken directly through tobacco-specific legislation), aff'd 120 S. Ct. 1291 (2000).
tobacco companies to demonstrate recognition that nicotine has powerful pharmacological effects. For example, according to the FDA's Executive Summary, manufacturers recognized that nicotine is "a powerful pharmacological agent with multiple sites of action" and "a physiologically active... substance... [which] alters the state of the smoker by becoming a neurotransmitter and a stimulant." Even in 1996, when the FDA chose to assert its regulatory jurisdiction over tobacco products, evidence existed which proved manufacturers' knowledge of nicotine's powerful effects.

Since 1996, tobacco litigation has resulted in more company documents surfacing that reveal manufacturer knowledge about the addictive nature of their product. For example, internal memoranda from a cigarette producer revealed that several tests were done in the late 1970's and early 1980's to "[d]etermine the minimum level of nicotine that will allow continued smoking" and also note that "smoking is both physiologically and psychologically motivated," and that when nicotine levels drop too low 'smokers will quit.' Even as litigation continues regarding whether tobacco is a drug or device, these manufacturer documents reveal that they clearly knew their products both affected the structure and function of the body and were used by consumers as drug delivery devices.

FDA findings also revealed that tobacco companies specifically designed their products to deliver "a pharmacologically active dose of nicotine to the smoker." Manufacturer experiments included tests on how to negotiate nicotine and tar levels as well as ammonia manipulation for increasing "free" nicotine levels to smokers. The FDA contends

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149 See Nicotine: Jurisdictional Determination, supra note 4, at 44,637.
150 Id. (citing comments regarding nicotine's addictive qualities in Philip Morris' internal documents).
151 Tobacco companies such as Brown & Williamson acknowledged the dangers of smoking and launched a web site to educate consumers on the health risks of smoking. See Suein L. Hwang, Tobacco Firm Gives Frank Advice Online, WALL ST. J., Apr. 9, 1999, at B1.
152 Doug Campbell, Lorillard Documents Revealing: Documents Discuss Nicotine Levels and Marketing to Teens, GREENSBORO NEWS & RECORD, June 28, 1998, at A1, A8 (citation omitted).
153 Nicotine: Jurisdictional Determination, supra note 4, at 44,640-41. The FDA included evidence of blending techniques and filter/ventilation systems that deliver high amounts of nicotine. See id. at 44,641.
154 See id. at 44,641.
that tobacco companies intended for their products to be used as drug delivery devices.\textsuperscript{155}

VI. IS THERE A SIMPLE ANSWER TO REGULATION?

The Supreme Court and the Fourth Circuit’s failure to find that the FDA had jurisdiction over tobacco products stemmed directly from congressional inaction and prior actions by the FDA negating assertion of jurisdiction.\textsuperscript{155} Both courts determined that the FDA was “attempting to stretch the Act beyond the scope intended by Congress.”\textsuperscript{155} The courts also found that the agency’s rationale for finding authority to regulate tobacco products would require the FDA to ban cigarettes. Such a finding was inconsistent with one of its missions established by Congress—to ensure the safety and efficiency of drugs and devices.\textsuperscript{158} The courts also noted that the regulations proposed by the FDA conflicted with the current regulatory practice of eliminating dangerous drugs.\textsuperscript{159} Furthermore, the regulations were contrary to the agency’s past stance that the FDA was not the proper authority to regulate tobacco products.\textsuperscript{160} It appears that the appellate court’s reasons are inconsistent with the FDA’s ability to conform to changing times and adapt regulatory techniques to meet new scientific findings.

Past agency policy regarding tobacco should not be held to dictate all future regulatory schemes.\textsuperscript{161} New findings show,


\textsuperscript{157} Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d at 167 (4th Cir. 1998), aff’d, 120 S. Ct. 1291 (2000).

\textsuperscript{158} See FDA v. Brown & Williamson Tobacco Corp., 120 S. Ct. at 1297-99 (opining that the FDA wants to assert jurisdiction in order to regulate an industry constituting a significant portion of the American economy and that the FDA would then have the authority to ban cigarettes and all smokeless tobacco), affg 153 F.3d 155, 166-67 (4th Cir. 1998).

\textsuperscript{159} See id. (noting that “based on the FDA’s characterization of tobacco products as unsafe, it is impossible to create regulations which will provide a reasonable assurance of safety[,]” and therefore it is impossible for the FDA to promulgate regulations that comply with the FDCA).

\textsuperscript{160} See id.

unlike past agency information, that smoking affects the structure and function of the body. Secondary findings show manufacturers intend this to be the case. The argument that congressional intent prohibits FDA regulation over tobacco products is also misplaced. Congress's failure to explicitly extend to the FDA the authority to regulate tobacco does not mean that regulatory activity is barred indefinitely. The regulatory techniques, though controversial, fulfill the overall intent of the FDCA: to protect consumers who are "unable to protect themselves."

If manufacturers discover a formula to make safer cigarettes, should the FDA regulate this type of product? If the FDA can regulate these products, will smoking increase? These are only a few questions regarding FDA regulation. Upon examination of these questions, commentators have agreed that significant price increases might deter smoking and, hence, reduce nicotine addiction in the United States.

Critics have noted that the best methods of cigarette control are negative advertisements, rather than a ban on specific advertisement forms. Perhaps this is a more realistic answer.

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162 See Regulations Restricting the Sale of Tobacco, supra note 7, at 44,397 (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897) ("FDA has determined that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, within the meaning of the act's definitions of 'drug' and 'device.' The nicotine in cigarettes and smokeless tobacco is a 'drug,' which produces significant pharmacological effects in consumers.").

163 See id. at 44,630 (noting that "[m]anufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine and mood alteration, and that consumers use their products primarily to obtain the pharmacological effects of nicotine").

164 See Coyne Beahm, Inc., 966 F. Supp. at 1384 (finding that "the text of the FDCA, its legislative history, and the body of evidence consisting of FDA's representations to Congress, unenacted bills, and statements by members of Congress do not clearly indicate that Congress intended to withhold from FDA the authority to regulate tobacco products").


166 See Jon D. Hanson & Kyle D. Logue, A Critique of the Proposed Tobacco Resolution and a Suggested Alternative, 41 L. QUAD. NOTES 76, 81 (1998).

167 See id.

168 See id. (noting that "[t]he proposed resolution arguably includes an incentive-based component, insofar as the costs imposed on manufacturers are required to be passed through to consumers in the form of a price hike").

169 See Mark A.R. Kleiman & Aaron J. Saiger, Drug Legalization: The Importance of Asking the Right Question, 18 HOFSTRA L. REV. 527, 549 (1990) (stating that negative advertising is a more powerful deterrent to drug abuse than a ban on advertising).
to regulation. Nevertheless, the answer to regulatory techniques is a complex issue due to the powerful social implications presented by tobacco use.\(^{170}\) The prevention of smoking must be delicately handled and in a manner suitable to government objectives and existing regulatory techniques. Tobacco addiction, however, can no longer be ignored. A multifaceted examination of consumer use, foreseeability, and closted manufacturer findings, must be considered when determining whether tobacco or any other product meets the "drug" or "device" criteria and should hence, be regulated.

How should Congress be guided? The United States Supreme Court and the Fourth Circuit relied on the FDA's prior regulatory schemes, congressional inaction, and tobacco-specific legislation.\(^{171}\) That is, these courts focused on historical actions by the FDA and congressional inaction and concluded that the FDA "exceeded the authority granted to it by Congress."\(^{172}\) In so doing, the FDA's rulemaking to regulate tobacco as a "drug," "device" or "combination product" could not stand.\(^{173}\) The follow-up examination of the FDA's past bouts with tobacco regulation is also problematic. The Fourth Circuit ignored, and the United States Supreme Court did not reach the issue of, newly acquired evidence regarding the FDA's jurisdiction over tobacco and the Agency's regulatory premise.\(^{174}\)

Comparison of the district court's decision with that of the United States Supreme Court leads to the conclusion that Coyne used a more comprehensive analysis. Coyne advanced the jurisdictional analysis a step past the FDA's prior actions and congressional inaction.\(^{175}\) In its analysis, the Coyne court

\(^{170}\) See FDA v. Brown & Williamson Tobacco Corp., 120 S. Ct. 1291, 1306-10 (2000) (explaining that such a delegation by Congress would have widespread economic and political implications).

\(^{171}\) See id., affg 153 F.3d 155, 161 (4th Cir. 1998).


\(^{174}\) See Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d. at 161 (ignoring the FDA's evidence that tobacco was intended to effect the body, and therefore tobacco products fall under the literal definitions of drug or device), affd 120 S. Ct. 1291 (2000).

\(^{175}\) See Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1381 (M.D.N.C. 1997),
determined that tobacco products fall within the "drug" or "device" definition of the FDCA.\textsuperscript{176} Coyne also concluded "that [the] FDA adequately and properly supported its finding of intended use with evidence of foreseeability and consumer use."\textsuperscript{177} The Coyne analysis appears more complete and legally realistic and serves as a sound basis for Congress to give the FDA authority to regulate tobacco.

CONCLUSION

Congress, as the court did in Coyne, must look at the "big picture" regarding tobacco regulation. Although prior tobacco legislation and congressional inaction remain important considerations, they do not solely justify the conclusion that the FDA lacks authority to regulate tobacco. Undoubtedly, a regulatory scheme with adequate resources could help curb America's deadliest preventable killer. Obviously, this is now up to Congress to do so through specific legislation affording FDA an explicit grant of authority.

\textsuperscript{176} See id. at 1388.
\textsuperscript{177} Id. at 1392.